

KASM® Knee Articulating Spacer Mold Surgical Technique



The following technique is a general guide for proper use of KASM® Knee Articulating Spacer Molds. It is expected that the surgeon is already familiar with the fundamentals of revision total knee replacement. Each patient represents an individual case that may require modification of the technique according to the surgeon's judgment and experience.

Please see the KASM Instructions for Use for intended uses, indications, device description, contraindications, precautions, warnings, and potential risks associated with KASM.

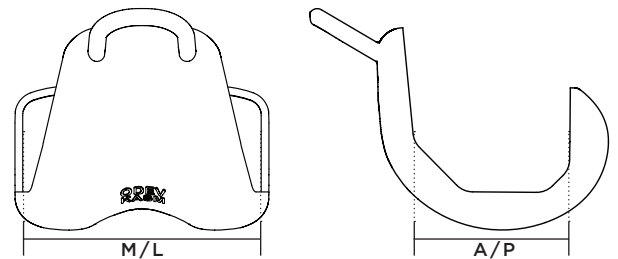
US Federal Law restricts this device to sale by or on the order of a physician.

Remove previously implanted components and residual bone cement from the infected joint. Clean and prepare the infected area using pulsatile lavage and debridement as necessary before implanting the cement spacer.

Select the appropriate KASM by taking the previously explanted component and comparing it to the dimensions of the femoral spacer mold. This will allow you to produce a temporary cement spacer required to fill the space vacated by the explanted prostheses while allowing sufficient bone coverage. Please refer to the reference chart (see table below) to assist in appropriately indicating the size desired.

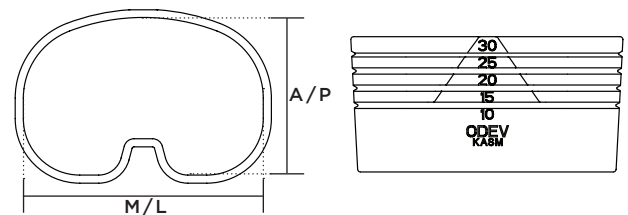
KASM Femoral Final Spacer Dimensions

Item Number	Size	M/L Dimension	A/P Dimension
669-1060	Small	60mm	37mm
669-1067	Medium	67mm	44mm
669-1075	Large	75mm	53mm



KASM Tibial Final Spacer Dimensions

Item Number	Size	M/L Dimension	A/P Dimension
669-2058	Small	58mm	39mm
669-2070	Medium	70mm	45mm
669-2081	Large	81mm	52mm



Prepare the bone cement mixture according to the manufacturer's instructions. It is recommended that two cement packets are used for each mold (see table above).

When the bone cement becomes doughy and no longer sticks to surgical gloves, form a ball with the cement and place it into the middle of the femoral articulating spacer mold. Manually press the cement ball to fill the entire femoral mold, taking care to push out any air pockets as the cement is pressed into the mold. The transparency of the femoral mold allows visualization of the articulating surface to verify full coverage of cement into the mold. Cement should completely fill the mold and allow enough overflow of cement to ensure adequate bone coverage when the mold is placed onto the femur. Before the cement fully cures, it will remain doughy but become less malleable (late doughy phase). When the cement reaches the late doughy phase, place the femoral articulating spacer mold onto the distal femur. Apply light pressure to the mold to secure it to the distal femur. Care should be taken to prevent the bone

cement from penetrating deeply into the distal femur to ease removal during the second stage of the revision procedures. Thoroughly remove excess cement from around the spacer mold. Allow the cement to completely cure, then remove the spacer mold.

The proper thickness for the tibial mold is determined by measuring the thicknesses of the explanted tibial insert and tibial baseplate. Create a tibial spacer thickness relative to this measurement, taking into consideration the desired soft tissue tension. Please note the tibial spacer should be no less than 10mm thick.

Once the proper thickness is determined, fill the tibial mold with doughy cement to the appropriate thickness, taking care to not permit bubbles or trapped air to produce defects in the cement spacer surface by manually pressing the cement into the mold.

Based on surgeon preference the cement spacer may be fixed to the tibia using two methods.

Method 1: Allow the tibial cement spacer to cure completely before releasing from the KASM mold. The cement spacer may be released from the mold by gently flexing the walls of the mold away from the cement body, then invert the tibial mold and press on the bottom surface of the mold to release. Do not impact the mold or the spacer to release it, as this could cause damage to the cement spacer.

Mix a second batch of bone cement and apply it to the tibial spacer once the cement has reached a doughy consistency. Apply the spacer to the tibia after the cement reaches the late doughy phase to prevent the cement from penetrating deeply into the bone. Take the patient through full range of motion to verify the patient has the desired stability and articulation of the two spacer components.

Method 2: Cut the tibial mold to the desired thickness then fill it with doughy cement. Before the cement fully cures, it will remain doughy but become less malleable (late doughy phase). When the cement reaches the late doughy phase, take the excess cement and apply it to the proximal tibia. Cement should completely cover the proximal tibia to ensure adequate bone coverage and provide additional fixation. Place the tibial spacer mold onto the tibia. Apply light pressure to the mold to secure it to the proximal tibia. Care should be taken to prevent the bone cement from penetrating deeply into the tibia to ease removal during the second stage of the revision procedures. The cement spacer may be released from the mold by gently flexing the walls of the mold away from the cement body. Take the patient through full range of motion to verify the patient has the desired stability and articulation of the two spacer components.

Remove excess cement from around the perimeter of the tibial spacer, taking care not to damage the spacer, and allow the cement to completely cure.

Thoroughly examine the femoral and tibial cement spacers and remove any excess cement using a knife, curette or small osteotome. Clean the joint space with pulsatile lavage to remove any cement particles.

REMOVAL TECHNIQUE FOR SPACER

To remove the tibial spacer, place a thin osteotome into the spacer/bone interface and tap lightly to loosen the spacer. After removing the tibial spacer, place a bone tamp or other blunt instrument against the superior rim on the anterior flange of the femoral spacer, aiming the instrument in the distal direction. Lightly impact the bone tamp to remove the femoral spacer.

Note: Prior to implantation of the 2nd stage revision components, thoroughly remove all cement debris that may have accumulated due to wear of the cement spacers.

WARNING

Failure to thoroughly remove cement debris may result in early failure of the 2nd stage revision arthroplasty.

PRECAUTIONS

KASM is to be used as a temporary cement knee spacer to fill the space vacated by the explanted prostheses. It is recommended for a period of 180 days or less. KASM is disposable and intended for single-use only.

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